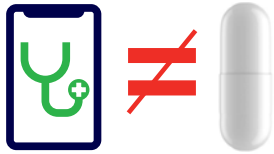


Recommendations for the reimbursement of health apps

Results of three 3-hour roundtables in 2023/2024 with 135 participants from 34 countries, focussing on 1) EU Member States' challenges in reimbursement of health apps, 2) multi-stakeholder solutions to these challenges, and 3) Member State decision-makers' perspectives.



1. Value

Acknowledge **apps can do things that pills can't** (and vice versa). Approximate with key stakeholders the added value of apps for health, public health and care (e.g. for health literacy, healthy behaviours, early diagnosis, personalized shared decision-making, self-management, remote consultations, symptom monitoring, multidisciplinary care delivery, treatment adherence, recovery, efficiency, primary and secondary use of (big) data), suggest accepted endpoints for studies and revisit this effort periodically.

2. Focus

Identify which (packages of) types of apps or their functional components for which health issues and which patients, and if applicable integrated in which care pathways are likely to add value. Prioritize these apps according to value added and explore existing policy goals, political support and day-to-day challenges. Start small, consider a pilot and assess the need for changes in or additions to policies and legislation.

3. Govern

Establish who or more specifically which multidisciplinary collaboration within or beyond the health authority is responsible for policymaking, evidence generation, innovation promotion, assessment, reimbursement, transparency, education and transformation (data usage). Manage change.

Overall health app quality score



4. Create

Enable manufacturers, clinicians and researchers to achieve more evidence-based, effective, value-adding apps and care pathways. Use adequate outcome measures to quantify the (potential) value of individual health apps and blended care pathways, and study how to create, capture and measure it. Harmonise accepted endpoints, comparators etc. where possible.

Healthy and safe



5. Assess

Determine quality requirements, assessors (internally and/or trusted third parties), assessment methods and what is sufficient evidence. Consider the trusted EU-initiated global CEN-ISO/TS 82304-2 framework as a basis, adding country specific requirements on top, to increase health system and manufacturer efficiency and avoid a duplication of efforts.

Secure data



6. Inform

Ensure intended users and prescribers are aware of and able to easily access positively assessed value-adding apps (e.g. quality label in app stores and frequently used trusted sources).



Health apps library

7. Fund

Allocate funding for value-adding apps and / or related blended care pathways. Consider innovative payment models, transparent criteria, and incentivizing all stakeholders involved (manufacturers, users, prescribers, providers) to achieve equitable sustainable use of value-adding apps at scale. Have pricing reflect the added value and needed investments.



8. Transform

Create the environment in which quality apps can deliver value: integrate into clinical guidelines, pathways, prescription practice, and care delivery. Educate and support health professionals and citizens to increase digital literacy, attain equitable sustained app use and capture value of data. Enable internet access, interoperability and safe data exchange with EHR systems. Use standards.

Easy to use



WHO European Member States: most important barriers to mApp integration into clinical practice ¹

(72% of European Member States (MS) lack regulatory oversight entity for mApps)

61% MS: lack of evidence effectiveness of mApps in clinical practice

75% MS: privacy, security (15% MS reported evaluating mHealth)

77% MS: lack of a trustworthy source to access effective mApps

WHO: evaluations should inform investment and implementation decisions

73% MS: lack of patient digital literacy

9. Measure to scale

Identify key value indicators and measure and present value transparently. Realise that the measurements will only reflect the attainable value when apps are quality-proven effective, where applicable integrated into care pathways, if users are sufficiently enabled, if the resulting data is used, if appropriate outcome measures, scope, comparators are utilised, etc. Explore, again in a multi-stakeholder effort, what are the promising next steps to capture the attainable value of health apps.

